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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/100,088	06/19/1998	PETER G. BROWN	1606.0020004	8182

26111 7590 05/14/2004

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

JONES, HUGH M

ART UNIT	PAPER NUMBER
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2128

25

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/100,088

Applicant(s)

BROWN, PETER G.

Examiner

Art Unit

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 18-27 of U. S. Patent 09/100,088, filed 6/19/1998, remain pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litt et al. (Applicant's IDS) or Bernstein et al. (of record) or Britt et al. (Applicant's supplemental IDS) in view of the taking of [Official Notice] and [Applicant's Own Admission].**

4. Litt et al. disclose: "Expert system and method for batch production scheduling and planning." See: abstract; fig. 2-7; col. 1-2 (details concerning the use of rule-based expert systems in process scheduling, batch scheduling, delivery dates, production constraints).

5. Bernstein et al. disclose a simulation-based decision support system for a speciality chemicals production plant that can be used in an off-line mode. Col. 1, page 1263 discloses that the simulation is carried out prior to any capital investment, and also

discusses the database, used in the simulation. Section 2 discloses scheduling and operations issues. Section 3 discloses a simulation execution module including simulation of batch processing and sequencing and a knowledge base.

6. Britt et al. disclose (abstract):

“A software system simulates and optimizes a processing plant design. The software system includes a plurality of equipment models for simulating each piece of equipment in the processing plant design. A sequential modular simulation routine executes the equipment models in a first mode to define a first set of values of the operating parameters of the processing plant design. An optimization routine executes the equipment models in a second mode. The optimization routine utilizes the first set of values for the operating parameters from the sequential simulation routine and subsequently determines values of the operating parameters at which the processing plant design is optimized. The equipment models after execution by the sequential simulation routine and optimization routine store the first and second sets of values for the operating parameters in a common plant model file. Hence, the plant model file holds values computed during the sequential simulation routine as well as those computed during the optimization routine.”

Col. 4, line 36 to col. 5, line 26 disclose:

“Applicants have discovered that the better software system for simulating and optimizing process plant designs is one which:

a) solves the initial plant model through sequential modular simulation. This generates an initial point. and

b) generates an equation oriented plant model which is initialized from the solution in a). This equation oriented model is then used for data reconciliation, parameter estimation, optimization, and simulation.

Such a system provides an improvement over the prior art.

By way of summary, there are two basic parts to the present invention. The first basic part of the present invention enables the same equipment model to be used in both (i) a simulation by a sequential modular computation, and (ii) the simultaneous simulation (or optimization) of the entire plant model. In other words, each equipment model can be executed in two modes as follows.

Mode A:

Given equipment operating parameters and the feed conditions, the equipment (process unit) model solves for the product streams of the corresponding piece of equipment. This means that the equipment model can be executed as a part of the sequential modular computation of the plant model.

Mode B:

An equipment model is able to participate in the simultaneous simulation of the entire plant model by computing items which are needed by the simulator which solves the total plant model.

To that end, each equipment model of the present invention has a dual execution mode capability, as described in detail below. The second basic part of the present invention is that each equipment model, at the end of the plant simulation or optimization, stores the results to a plant model file, which is used with both modes of

the equipment model execution. This part of the present invention enables the solution of the sequential modular simulation and the solution of the simultaneous simulator/optimizer to be mutually shared. Hence, initial plant simulation is carried out by a sequential modular simulation. The results are stored in the plant model file. The results of the sequential modular simulation are then used as the initial, starting point for the simultaneous simulation and optimization of the plant model. Results obtained by the simultaneous simulation of the plant model are also stored in the plant model file. Therefore, one can use these results to run a sequential modular plant simulation.

In the present invention, initial simulation of a desired process plant by a sequential modular routine enables the convergence of the plant model (i.e., solution thereof) with a very small number of specifications or initial guesses entered by the plant model developer/engineer. This solution then serves as the starting point for the optimization of the plant model by the simultaneous simulation routine. Since the simultaneous simulation routine starts from a feasible point (solution by the sequential modular routine), the simultaneous simulator/optimizer converges to an optimum point in a robust manner."

See, also: fig. 1-2; col. 1, line 45 to col. 4, line 33.

17. The applied prior art does not disclose biopharmaceutical applications and details pertinent to biopharmaceutical applications. Applicant has admitted that (page 23, lines 13-27, specification) that the invention is a general simulation procedure for batch processes *other* than *just* for biopharmaceutical applications. Official Notice is taken that one of ordinary skill in the art at the time of the invention would recognize and

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choose the appropriate process and quality control variables as necessary for the particular application.

Response to Arguments (paper # 24)

18. Applicant's arguments filed 2/25/2004 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 18-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be:

directed to:

Dr. Hugh Jones telephone number (703) 305-0023, Monday-Thursday 0830 to 0700 ET, *or* the examiner's supervisor, Kevin Teska, telephone number (703) 305-9704. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, telephone number (703) 305-3900.

mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

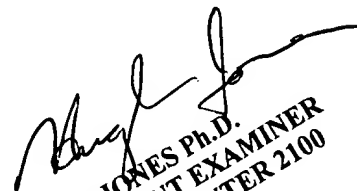
or faxed to:

(703) 308-9051 (for formal communications intended for entry)
or (703) 308-1396 (for informal or draft communications, please label "*PROPOSED*"
or "*DRAFT*").

Dr. Hugh Jones

Primary Patent Examiner

May 12, 2004


HUGH JONES Ph.D.
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 2100